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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MITSUBISHI TANABE PHARMA CORPORATION, *et al.*, Plaintiffs, v. SANDOZ INC., *et al.,* Defendants.	Civil Action No. 17-5319 (FLW) (DEA) (CONSOLIDATED) (Filed Electronically)

FINAL JUDGMENT

NOW THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over Plaintiffs Mitsubishi Tanabe Pharma Corporation, Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica NV, Janssen Research and Development, LLC, and Cilag GmbH International (collectively, "Plaintiffs") and Defendant Zydus Pharmaceutical (U.S.A.) Inc. ("Zydus") and the subject matter of this action.

2. For the reasons set forth in the Court's March 22, 2021 Memorandum Opinion (D.I. 243), Final Judgment is entered in favor of Plaintiffs and against Zydus on all claims and counterclaims with respect to United States Patent No. 7,943,788 ("the '788 patent"), United

States Patent No. 8,222,219 ("the '219 patent"), and United States Patent No. 8,785,403 ("the '403 patent"). The manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Zydus's Abbreviated New Drug Application ("ANDA") products that are the subject of ANDA Nos. 210541 and 210542 before the expiration of these patents would infringe claims 12 and 20 of the '788 patent, claim 22 of the '219 patent, and claim 26 of the '403 patent. Claims 12 and 20 of the '788 patent, claim 22 of the '219 patent, and claim 26 of the '403 patent are not invalid.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Zydus's ANDA Nos. 210541 and 210542 shall be no earlier than the latest date of expiration of the '788, '219, and '403 patents (currently July 14, 2027), including any periods of regulatory exclusivity, such as pediatric exclusivity under 21 U.S.C. § 355a, that the U.S. Food and Drug Administration ("FDA") may deem to apply in the future.

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Zydus and its affiliates, successors, partners, officers, agents, servants, employees, and attorneys, and other persons or entities in active concert or participation with any of them, are hereby enjoined from commercially manufacturing, using, offering to sell, or selling within the United States, or importing into the United States, the products that are the subject of ANDA Nos. 210541 and 210542 until the latest date of expiration of the '788, '219, and '403 patents (currently July 14, 2027). If Plaintiffs become entitled to new regulatory exclusivities, such as pediatric exclusivity under 21 U.S.C. § 355a, Plaintiffs may apply to the Court for further relief as may be appropriate, without prejudice to Zydus's right to object to such further relief. For the sake of clarity, nothing in this Judgment prohibits activity that falls within the 35 U.S.C. § 271(e)(1) safe harbor.

5. Within five days of the entry of this Final Judgment, Zydus shall inform the FDA of this Final Judgment and that, for ANDA Nos. 210541 and 210542, a Final Judgment has been entered that claims 12 and 20 of the '788 patent, claim 22 of the '219 patent, and claim 26 of the '403 patent are infringed and not invalid. Zydus shall provide confirmation of such communication to Plaintiffs within seven days thereof.

6. As the prevailing parties in this action, Plaintiffs may seek their costs subject to Paragraphs 7 and 8 in an amount to be determined by the Clerk of Court.

7. In the event that a party appeals this Final Judgment, any motion for attorney fees and/or costs, including any bill of costs or motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within 60 days after final disposition of any such appeal. The responding party shall have 45 days after filing and service of any such motion to respond, and the moving party shall have 21 days thereafter to file and serve a reply.

8. In the event that no party appeals this Final Judgment, any motion for attorney fees and/or costs, including any bill of costs or motion that this case is exceptional under 35 U.S.C. § 285, shall be considered timely if filed and served within 60 days after the expiration of the time for filing a notice of appeal under Fed. R. App. P. 3 and 4. The responding party shall have 45 days after filing and service of any such motion to respond, and the moving party shall have 21 days thereafter to file and serve a reply.

9. All pending motions and other outstanding requests for relief not specifically addressed herein are DENIED. This is a final, appealable judgment.

IT IS SO ORDERED this 5th day of April 2021.

/s/ Freda L. Wolfson
FREDA L. WOLFSON
United States Chief District Court Judge